UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

JILL A. WHITCOMB,

Plaintiff,

Case No. 17-CV-14

v.

ERIC HARGAN,
Acting Secretary of Health
and Human Services,

Defendant.

DEFENDANT'S RESPONSE TO PLAINTIFF'S MOTION FOR ATTORNEY FEES UNDER THE EQUAL ACCESS TO JUSTICE ACT

I. INTRODUCTION

This Court should deny Plaintiff's motion for attorney's fees and costs totaling $57,567.34 under the Equal Access to Justice Act (EAJA) because the Secretary's decision to litigate this case was substantially justified. Although the Court found that the Secretary erred in concluding that the requested continuous glucose monitor (CGM) did not meet the regulatory definition of Durable Medical Equipment (DME), such a finding does not automatically entitle Plaintiff to attorney fees and costs under EAJA. Indeed, the Secretary acted reasonably in reaching his decision that the requested CGM was not covered by Medicare because it does not serve a medical purpose. Specifically, in reaching his conclusion, the Secretary relied on the statutory language requiring that items and services be reasonable and necessary to diagnose or treat an injury or illness, he relied on the Centers for Medicare & Medicaid Services's (CMS) Medicare Benefit Policy Manual's interpretation of what it means to serve a medical purpose for Medicare coverage purposes, and he relied upon the evidence in the record confirming that the

data CGMs provide is unreliable and should not be used in treating diabetes. In light of the Secretary's reasonable position, Plaintiff is not entitled to a fee award under EAJA.

II. BACKGROUND

The facts in this case are undisputed. Plaintiff is a Medicare beneficiary diagnosed with Type I diabetes. AR 5, 25, 148, 285, 472. Additionally, she suffers from hypoglycemia unawareness. AR 249, 283, 472. Plaintiff requested that her Medicare Advantage (MA) organization, UnitedHealthcare/SecureHorizons (SecureHorizons), provide coverage for the long-term use of a CGM. Under the MA program, 42 U.S.C. § 1395w-21 *et seq.*, MA organizations are required to offer, at a minimum, the same benefits offered by Medicare Parts A and B. 42 U.S.C. § 1395w-22(a)(1); 42 C.F.R. § 422.100(c)(1). Additionally, MA organizations are required to comply with National Coverage Decisions (NCDs), general coverage guidelines included in Medicare manuals and instructions, and written coverage decisions of Medicare Administrative Contractors (MACs) with jurisdiction for claims in the geographic area in which services are covered under a MA plan. 42 C.F.R. § 422.101.

SecureHorizons denied Plaintiff's request for a CGM based on Policy Article A47238, which states that CGMs are precautionary devices not covered under Medicare's DME benefit. AR 266. The Secretary upheld SecureHorizons' decision denying coverage. Plaintiff challenged the Secretary's final decision before this Court. While the Court agreed that the Secretary correctly found that coverage for a CGM did not exist under NCD 40.2 or LCD L27231, the Court found that the Secretary erred in relying on Policy Article A47238 to deny coverage. Consequently, the Court remanded the case to the Secretary to assess whether the requested CGM is reasonable and necessary and not otherwise excluded from coverage.

Plaintiff requested over $26,000 in attorney fees after the Court issued its May 26, 2015 decision. Dkt. No. 53 (Plaintiff's Petition for Fees and Costs dated June 26, 2015). However, the Court found that even though the Secretary's position was ultimately unsuccessful, it was substantially justified. Dkt. No. 66 (Order Denying Fees and Costs dated September 9, 2015). Specifically, the Court held that it was reasonable for the Secretary to rely on a policy article to fill the coverage gap left by NCD 40.2 and LCD L27231. *Id.* Moreover, the Court held that the non-precedential decisions of other administrative law judges in similar cases did not result in the Secretary's position being not substantially justified. *Id.*

In response to the Court's May 26, 2015 decision, on August 28, 2015, the Council remanded the case to the ALJ for a determination regarding whether the requested CGM qualified as DME. AR 199-203. The Council stated that in analyzing whether Medicare coverage exists for an item or service, the relevant inquiry must first determine if the item or service falls within a statutory benefit category. AR 202. If it does, the adjudicator then decides if the item or service is reasonable and necessary. *Id.* In this case, the Council pointed out that the ALJ's focus had been on whether the requested CGM was reasonable and necessary. He did not address whether the CGM met the definition of DME. *Id.* Thus, the Council instructed the ALJ to:

> [C]onsider whether the Policy Article constitutes binding guidance for the Medicare Advantage Plan, pursuant to 42 C.F.R. section 422.101(b)(3). Only if the ALJ determines that the CGM systems meet the definition of DME, then should the ALJ analyze whether the CGM system is medically reasonable and necessary for the enrollee in this case, pursuant to the District Court's Order.

Id.

The ALJ found that the requested CGM qualified as DME. AR 20-35, 1152-1202. In addition to finding that the CGM qualified for coverage under the DME benefit category, the ALJ found that the CGM was reasonable and necessary for Plaintiff. AR 31-33. The ALJ noted that he was not required to give substantial deference to Policy Article A47238 because it is not a coverage determination. AR 33. The ALJ also noted that SecureHorizons was not bound by Article A47238 because it was not the type of guidance referred to under 42 C.F.R. § 422.101(b)(3). *Id.* Finally, despite this Court's ruling that NCD 40.2 and LCD L27231 did not provide coverage for CGMs, the ALJ found that they did not differentiate between home blood glucose monitors and CGMs. AR 33-34. The ALJ thus found that coverage was available for CGMs under NCD 40.2 and LCD L27231. *Id.*

SecureHorizons again appealed the ALJ's decision to the Council. AR 82-86. SecureHorizons argued that the specific CGM for which Plaintiff sought preauthorization, *i.e.* the Medtronic MiniMed System, is not covered under the Medicare DME benefit because it is a precautionary device that should not be used to make therapeutic decisions. AR 83-84. SecureHorizons pointed out that the FDA approval for the requested CGM stated, among other things, that it must be used with a blood glucose meter, no treatment decisions should be made or changed based on the results of the CGM's readings, and the results of the CGM's readings must be confirmed by a finger stick test. AR 84, 102. SecureHorizons acknowledged that Plaintiff had since obtained a Dexcom G4. AR 84. However, SecureHorizons added that the Dexcom G4 was also a precautionary device. *Id.* To support its position, SecureHorizons submitted the Dexcom G4's FDA approval which stated the readings from this system are not intended to replace the information obtained from a standard home blood glucose monitor. AR 84, 104. Rather, the Dexcom G4 is intended to compliment the information obtained from the traditional

test. *Id.* In response, Plaintiff argued that the CGM is the standard of care for Type I diabetics with hypoglycemia unawareness. AR 76-77. Plaintiff acknowledged, though, that CGMs need to be used in connection with finger stick tests. *Id.*

After reviewing the record, the Council concluded that CGMs do not qualify for coverage because they are not DME, which means that CGMs, even if considered medically necessary, are not covered by Medicare because they do not fit in a defined benefit category. AR 9. The Council explained that DME must be primarily and customarily used for a medical purpose. AR 10. The Council stated that CGMs are not primarily and customarily used for a medical purpose because they are precautionary items. AR 10. While the Council acknowledged that the term precautionary is not statutorily defined, the Council found that this means that the device itself must be used for a medical purpose. Here, the Council found that the requested CGM was not used for a medical purpose because it did not measure glucose in the blood and therapeutic decisions were not supposed to be made based on its readings, without first confirming blood glucose levels with a finger stick test. In other words, the CGM was not a substitute for finger stick tests. Rather, the CGM simply provided an added precaution. AR 10. The Council added that the ALJ erred by ignoring this Court's holding that neither NCD 40.2 nor LCD L27231 provide coverage for CGMs. AR 10.

After briefing and oral argument, this Court held that the Secretary erred in concluding that the requested CGM did not satisfy the regulatory requirements for DME set forth at 42 C.F.R. § 414.202. Dkt. 19 (Decision and Order). Specifically, the Court found that the requested CGM satisfied the requirement that it be primarily used to serve a medical purpose because the Secretary did not articulate a non-medical purpose for the CGM. *Id.* at 11-12. Additionally, the Court held that the regulations do not exclude coverage for equipment that

must be used in conjunction with another device. *Id.* at 13. Finally, the Court found that the Secretary's decision not to cover a CGM for Plaintiff was arbitrary and capricious because the device was covered for other beneficiaries. *Id.* at 14-15. Having prevailed before this Court, Plaintiff filed the instant application for fees under EAJA.

III. ARGUMENT

A. The Equal Access to Justice Act

The EAJA is not an automatic fee shifting statute. *See Federal Election Comm'n v. Rose*, 806 F.2d 1081, 1087 (D.C. Cir. 1986); *Commissioner, I.N.S. v. Jean*, 496 U.S. 154, 155 (1990). The EAJA provides for an award of attorney fees and other expenses to a party who prevails in litigation against the United States if: (1) he was a "prevailing party"; (2) the government's position was not "substantially justified"; (3) there exist no special circumstances that would make an award unjust; and (4) he filed a timely application. 28 U.S.C. §§ 2412(d)(1)(A),(B).

In the present case, Plaintiff is a prevailing party because the magistrate judge remanded the case to the Secretary pursuant to Sentence 4 of 42 U.S.C. § 405(g). *Shalala v. Schaefer*, 509 U.S. 292, 301-302 (1993). Additionally, no special circumstances would make an award unjust and the application for fees was timely filed. 28 U.S.C. § 2412(d)(1)(A). Thus, the primary issue before the Court is whether the Secretary's position was substantially justified. *Id.*

The Secretary bears the burden of showing that his position was substantially justified. *Marcus v. Shalala*, 17 F.3d 1033, 1036 (7th Cir. 1994). Although the phrase "substantially justified" is not defined in the EAJA, the Supreme Court has explained that the government's position is substantially justified if it is "'justified in substance or in the main'—that is, justified to a degree that could satisfy a reasonable person." *Pierce v. Underwood*, 487 U.S. 552, 565

(1988). In offering further guidance regarding the substantially justified standard, the Supreme Court stated:

> [A] position can be substantially justified even though it is not correct, and we believe that it can be substantially (i.e., for the most part) justified if a reasonable person could think it correct, that is, if it has a reasonable basis in law and fact.

Id. at 566 n. 2. Thus, substantially justified does not mean "justified to a high degree," but rather is satisfied if there is a "genuine dispute" or if reasonable people could differ as to the appropriateness of the contested action. *Stein v. Sullivan,* 966 F.2d 317, 320 (7th Cir. 1992) (citing *Underwood*, 487 U.S. at 565).

Moreover, a loss on the merits does not equate with a lack of substantial justification. *See Underwood*, 487 U.S. at 569 ("[O]bviously, the fact that one agreed or disagreed with the Government does not establish whether its position was substantially justified. Conceivably, the agency could take a position that is not substantially justified, yet win; *even more likely, it could take a position that is substantially justified, yet lose.*") (emphasis added). Therefore, a court's statement in its merits decision that the government did not have a rational ground for its decision does not imply a lack of substantial justification for the agency's position. *Kolman v. Shalala*, 39 F.3d 173, 177 (7th Cir. 1994).

Significantly, the substantial justification standard is distinct from the substantial evidence standard, which governs review of the Secretary's final decision. *Cummings,* 950 F.2d at 498. As *Cummings* observed, these two standards of review "are used at different stages and involve different tests." *Id.* At the EAJA stage, the court must take a fresh look at the case from the EAJA perspective and reach a judgment independent from the ultimate merits decision. *Rose,* 806 F.2d at 1087-90. In other words, at the EAJA stage, the test is "whether the agency had a rational ground for thinking it had a rational ground for its action." *Kolman,* 39 F.3d at

177. As such, this Court should deny the application for EAJA fees as long as the Secretary reasonably argued this case. *See Underwood*, 487 U.S. at 565; *Stein*, 966 F.2d at 320.

B. The Secretary's Position Was Substantially Justified

When considering whether to award attorney fees under EAJA, the court determines whether the government's position during the administrative and litigation phases was substantially justified. 28 U.S.C. § 2412(d)(2)(D); *Cummings*, 950 F.2d at 496. However, the court need only make one determination as to whether the government's position as a whole was substantially justified during the entire civil action. *Commissioner, I.N.S. v. Jean*, 496 U.S. 154, 159 (1990).

The Secretary's position throughout the administrative proceedings and the litigation before this Court has been substantially justified. During the most recent administrative proceedings and before this Court, the key issue was whether a CGM qualifies as DME under 42 C.F.R. § 414.202. The focus has been on whether the requested CGM "is primarily and customarily used to serve a medical purpose." 42 C.F.R. § 414.202(3). The Secretary's position that the requested CGM did not serve a medical purpose for Medicare coverage purposes, while ultimately unsuccessful, was substantially justified.

As a starting point, it is important to recall that in order for any item or service to be covered by Medicare, the item or service must be reasonable and necessary for the diagnosis or treatment of an injury or illness. 42 U.S.C. § 1395y(a)(1)(A). As the Secretary explained, the requested CGM does not *treat* Plaintiff's diabetes. Indeed, the undisputed evidence established that CGMs should not be relied upon to make any treatment decisions. The manufacturer's instructions for the Medtronic MiniMed and the Dexcom G4 both warn individuals that their treatment regimens should not be altered solely on the basis of the CGMs' readings. AR 84, 104.

Thus, the Secretary's argument that Medicare coverage was unavailable for the requested CGM was directly related to the plain statutory language guiding all coverage decisions.

Moreover, the medical literature submitted by Plaintiff confirmed that the Secretary correctly determined that CGMs should not be used to make treatment decisions. For example, the American Diabetes Association (ADA) recognized that CGMs should only be used as a supplemental tool for managing hypoglycemia unawareness. Record at 18, ADA Position Paper. In other words, the ADA agreed with the Secretary that CGMs were not technologically advanced enough to be used in treating diabetes. Similarly, a study published in the *Journal of Diabetes Technology & Therapeutics* directed participants to "use CGM data as an adjunct to, and not a replacement for [self-monitoring if blood glucose] finger sticks when making diabetes-related treatment decisions (*e.g.* insulin does modifications)" and concluded that the accuracy of CGMs does not yet equal the accuracy of self-monitoring of blood glucose. Record at 18, Attachment 1. Thus, the Secretary reasonably concluded that coverage does not exist for the requested CGM because the device itself is not used to diagnose or treat an injury or illness, as required by 42 U.S.C. § 1395y(a)(1)(A).

Similarly, the Secretary's position that the requested CGM does not serve a medical purpose was substantially justified even if it, too, was unsuccessful. Again, as noted above, the Court's review of the Secretary's position in connection with a petition for fees is not to determine if the Secretary's position was ultimately correct. Rather, the Court is reviewing the Secretary's position and determining whether the Secretary's position was "justified to a degree that could satisfy a reasonable person." *Pierce*, 487 U.S. at 565. Here, the Secretary acted reasonably when relying on the Medicare Benefit Policy Manual (MBPM) in determining that the requested CGM does not serve a medical purpose. Neither the Medicare Act nor its

implementing regulations define the parameters of what it means "to serve a medical purpose." The Secretary is in the best position to define the parameters of coverage because of his technical expertise and because he has an obligation to preserve the limited resources of the Medicare Trust Fund. In other words, as the Secretary explained, determining coverage issues is not an easy task. Regardless, the Secretary must make difficult decisions when it comes to coverage issues because Congress did not intend for Medicare to cover every item or service that a beneficiary requests. Consequently, in defining the parameters of what it means to serve a medical purpose, it was entirely reasonable for the Secretary to look to the MBPM for guidance. This is so because the MBPM is issued by CMS, the agency responsible for administering the Medicare program. CMS's guidance regarding the type of equipment that is considered to serve a medical purpose states, "first-aid or precautionary-type equipment (such as preset portable oxygen units) . . . are considered non-medical in nature" and therefore, "are not considered covered DME." MBPM, Ch. 15, § 110.1-B-2. In light of this guidance, it was not unreasonable for the Secretary to conclude that the requested CGM was precautionary, and therefore non-medical in nature, given the undisputed evidence establishing that CGMs cannot be relied upon to make treatment decisions. Instead, the Secretary equated the CGM to an alarm that prompted Plaintiff to take an additional action in order to treat her diabetes, thereby rendering the CGM a precautionary device. While the Secretary accepts that this Court disagreed with his position, the Court's decision does not necessarily mean that the Secretary was not substantially justified in his position.

The Secretary additionally submits that the consistency of his argument throughout the administrative proceedings and before this Court highlights his thoughtful, reasonable approach. Moreover, the Secretary's decision to cover therapeutic CGMs confirms the Secretary's

consistent position. As the Secretary has explained, CMS Ruling No. 1682 provides coverage for therapeutic CGMs. The reason coverage exits for the therapeutic CGMs is because they may be relied upon to make treatment decisions. Therefore, therapeutic CGMs meet the statutory requirement that items and services be reasonable and necessary for the diagnosis or treatment of an injury or illness. The rationale used as the basis for covering therapeutic CGMs is the same as the rationale for denying coverage for the requested CGM. In other words, logic dictates that if the device that cannot be relied upon to make a treatment decision is not covered, then the device that can be used to make treatment decisions should be covered. This is because both satisfy the statutory requirement that coverage is only provided when an item or service is used to diagnose or treat an illness or injury.

Finally, the Secretary submits that the fact that unrelated administrative proceedings led to the coverage of CGMs for other beneficiaries does not render the Secretary's position not substantially justified. Magistrate Judge Duffin specifically held that non-precedential decisions of other administrative law judges do not render the Secretary's position not substantially justified. Just as the findings of other administrative law judges do not render the Secretary's position not substantially justified, the decision in *Finnigan v. Burwell*, 189 F.Supp.3d 201 (D. Mass. 2016) also does not render the Secretary's position not substantially justified. The Supreme Court in *Pierce* stated:

> Obviously, the fact that one other court agreed or disagreed with the Government does not establish whether its position was substantially justified. Conceivably, the Government could take a position that is not substantially justified, yet win; even more likely, it could take a position that is substantially justified, yet lose.

Pierce, 487 U.S. at 568.

Overall, the Secretary's position was substantially justified even if it was rejected by this Court. The Secretary's argument that the requested CGM should not be covered is supported by the plain language of the Medicare Act and the sub-regulatory guidance that informs the public as to what types of equipment are primarily and customarily used to serve a medical purpose. Accordingly, the Secretary respectfully requests that this Court deny Plaintiff's request for over $50,000 in fees and costs.

B. Attorney Parrish Is Not Entitled To A Fee Enhancement

In the event that this Court finds that the Secretary's position was not substantially justified, the Secretary urges this Court to hold that Plaintiff's request for over $50,000 in fees and costs is excessive. The EAJA provides that the amount of attorneys' fees awarded:

> shall be based upon prevailing market rates for the kind and quality of the services furnished, except that . . . attorney fees shall not be awarded in excess of $125 per hour unless the court determines that an increase in the cost of living [since 1996, when the current version of the Act was passed] or a special factor, such as the limited availability of qualified attorneys for the proceedings involved, justifies a higher fee.

28 U.S.C. § 2412(d)(2)(A)(ii).

While the EAJA clearly sets the hourly rate for an attorney to be $125, the Secretary does not dispute the appropriateness of adjusting that amount to take into account a cost of living adjustment. Thus, if an award of fees is granted, the Secretary accepts Plaintiff's calculation of the hourly rates as adjusted by the Consumer Price Index (CPI).

The Secretary, though, disputes that a special factor enhancement should be applied for the work performed by Attorney Deborah Parrish. As the Supreme Court stated in *Pierce*, the EAJA "is not designed to reimburse reasonable fees without limit." *Pierce*, 487 U.S. at 573. Although the statute specifically sets a $125 cap on the hourly rate, adjustments can be made for

cost of living or if a special factor is present. In *Pierce*, the Supreme Court found that an upward adjustment based on a special factor is only available if the availability of qualified attorneys is limited and if the nature of the case makes it necessary to retain the services of attorneys qualified in "some specialized sense, rather than just in their legal competence." *Id.* at 572. The Court stated:

> We think it [the special factor] refers to attorneys having some distinctive knowledge or specialized skill needful for the litigation in question – as opposed to an extraordinary level of the general lawyerly knowledge and ability useful in all litigation.

Id. The Seventh Circuit has interpreted *Pierce* to require an inquiry into whether a case presents such unusual circumstances that it requires an attorney with "specialized training and expertise unattainable by a competent attorney through a diligent study of the governing legal principles." *Raines v. Shalala*, 44 F.3d 1355, 1361 (7th Cir. 1995).

Here, Attorney Parrish argues that she is entitled to an upward adjustment in her fees because of her degree in Biomedical Engineering and her previous experience at the Department of Health and Human Services. According to Attorney Parrish, her education uniquely qualified her to understand the present litigation and the complexities of product approval by the Department of Health and Human Services. Although the Secretary acknowledges Attorney Parrish's accomplishments, they do not support the significant upward adjustment she seeks.

Contrary to Attorney Parrish's assertion, the present case does not require that an attorney have any specific scientific expertise. This is because the issue was not whether a CGM should be approved for public use, but whether a specific CGM (that is already approved by the FDA) should be covered by Medicare under the DME benefit. Without having a scientific background, it is easy to understand that a CGM operates by continually measuring the glucose levels in the

fluid just below a person's skin. When the person's glucose level falls outside a predetermined level, an alarm sounds to alert the person that a finger stick test should be performed. Because the present case did not delve deeper into the inner workings of a CGM, Attorney Parrish's scientific background was not necessary to her providing effective counsel on behalf of Plaintiff.

In other words, an attorney with an understanding of administrative and federal court litigation would likely have been able to adequately represent Plaintiff regardless of possessing specific scientific knowledge. Indeed, it is unclear why Attorney Pledl required co-counsel in light of his statement that he has 36 years of experience in federal court litigation, including extensive experience in administrative litigation in the disability law and Medicaid coverage contexts. By retaining two attorneys, Plaintiff unnecessarily increased the overall fees in the case, which would have been approximately $7,000 had Attorney Pledl handled the case on his own. Instead, the requested fees exceed $50,000 for a device valued at less than $3,000.

Additionally, it is also difficult to understand why Plaintiff sought counsel from another state to serve as co-counsel. Attorney Parrish suggests that Plaintiff could not locate an attorney in Milwaukee who could understand how CGMs operate and who had experience handling Medicare coverage cases. According to the Milwaukee Bar Association, there are approximately 4,000 attorneys in Milwaukee County. *See* *http://milwbar.org/about.php*. It is unreasonable to suggest that not one of the 4,000 attorneys located in Milwaukee County could understand the purpose of a CGM or how to navigate Medicare's appeal process. Again, had Plaintiff retained local counsel to serve as co-counsel, the fees being requested would be substantially less (and there would not be $700 in travel costs). This is supported by Attorney Pledl's statement that his prevailing rate is $300 after 36 years of experience, rather than the $500-$525 charged by Attorney Parrish.

If an award of fees is granted, the Secretary urges this Court to deny the application of a special factor enhancement to the hourly rate charged by Attorney Parrish. This case involved a straightforward review of the Secretary's final decision denying coverage for a CGM. No scientific knowledge or otherwise specialized skills were required to adequately represent Plaintiff. Accordingly, Attorney Parrish's request for an enhanced fee should be denied.

IV. CONCLUSION

The Secretary's position throughout the administrative proceedings and before this Court was and is substantially justified. While this Court disagreed with the Secretary's position, that disagreement does not automatically equate to a fee award under the EAJA. If, however, the Court finds that the Secretary's position was not substantially justified, the Secretary urges this Court to deny Attorney Parrish's request for an enhanced fee and only award reasonable costs based on the rate set forth in the EAJA (with an adjustment for cost of living).

Dated this 21st day of December, 2017.

Respectfully submitted,

GREGORY J. HAANSTAD
United States Attorney

By: /s/ Lisa T. Warwick
Lisa T. Warwick
Assistant United States Attorney
Eastern District of Wisconsin
517 E. Wisconsin Ave.
Milwaukee, WI 53202
State Bar No. 1017754
(414) 297-1700
Facsimile: (414) 297-4394
Lisa.warwick@usdoj.gov

Of Counsel:

Brian Stimson
Acting General Counsel

Alan S. Dorn
Chief Counsel, Region V

Teresa M. Vargas
Assistant Regional Counsel
Department of Health and Human Services
Office of the General Counsel
Byron G. Rogers Federal Building
1961 Stout Street
Room 08-148
Denver, CO 80294